REMARKS

Status of the Claims

Claims 1-3, 46-51, 67, and 70-79 are under consideration in this application, claims 1, 46-51 and 74-77 are allowed, and claims 2, 3, 67, 70-73, 78 and 79 are rejected. After entry of the amendments made herein, claims 1-3, 46-51, 67, and 70-77 will be under consideration in this application, claims 78 and 79 having been cancelled.

Claims 1, 2, and 3 have been amended to change the number of the first nucleotide in the nucleic acid sequence specified by element 1 in each of these claims from 90 to 91. This amendment is supported by the specification, e.g., at page 67, line 27. In addition, element (2) has been deleted from claims 2 and 3 and has been replaced by element (2) as recited in claim 1. This amendment is supported by the specification and the claims as originally filed, e.g., element (3) of claim 1 as originally filed, claims 2 and 3 as originally filed, and SEQ ID NO:10 in the Sequence Listing.

35 U.S.C. §101 rejection

Claims 2, 3, 78, and 79 stand rejected on the grounds that they are allegedly directed to non-statutory subject matter.

From the comments on page 2, paragraph 2, of the Office Action, Applicants understand the Examiner's position to be that claim 2 and claim 3 read on a naturally occurring cell and a naturally occurring polypeptide, respectively. Applicants respectfully submit that, from the definition of the word "transformed" for the purposes of the instant specification (see page 35, lines 9-20), it is clear that claim 2 does not read on a naturally occurring cell. Nevertheless, in order to expedite prosecution of the instant application, Applicants have: (a) amended claim 2 to specify that the cell comprises a recombinant nucleic acid molecule; and (b) amended claim 3 to specify that the polypeptide is expressed from the cell of claim 2 and is encoded by the recombinant nucleic acid molecule that the cell comprises. These amendments are supported throughout the specification, e.g., at page 7, lines 15-23; page 9, line 26, to page 10, line 17; page 13, line 23, to page 14, line 13; page 71, line 1, to page 72, line 4; Example 12; and Example 16.

In light of the above amendments, Applicants submit that it is very clear that claim 2 and claim 3 do not read on naturally occurring entities and thus request that the rejection under 35 U.S.C. §101 be withdrawn.

35 U.S.C. §112, first paragraph, rejections

(a) Claims 2, 3, 78, and 79 stand rejected: (i) on the grounds that the specification allegedly does not enable a person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with the claims; and (ii) as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention.

From the text on page 2, paragraph 4, to page 6, paragraph 6, of the Office Action, Applicants understand the Examiner's position to be that the specification provides neither written description nor enablement for a cell comprising, or a polypeptide encoded by, a nucleic acid molecule containing a nucleic sequence specified by element (3) of claims 2 and 3. Applicants respectfully disagree with this position. However, in order to expedite prosecution of the instant application, they have deleted element (3) from claims 2 and 3, renumbered the elements of these claims, and cancelled claims 78 and 79 without prejudice to their being prosecuted in a separate application. No new matter is added by these amendments.

(b) Claims 2, 67, 70-73, and 78 stand rejected on the grounds that the specification allegedly does not enable a person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with the claims.

As indicated above, claim 78 has been cancelled.

From the comments on page 8, paragraph 7, of the Office Action, Applicants understand the Examiner's position to be that claims 2 and 67 read on cells *in vivo* as well *in vitro* but that the relevant cells *in vivo* are not enabled by the specification. Applicants strongly disagree with the position that the cells *in vivo* are not enabled by the specification. Thus, for example, with respect to claim 67, subsequent to the priority date of the instant application, others have created pigs with functionally inactivated α-1,3-galactosyltransferase genes. All the cells of such pigs

comprise a disrupted α-1,3-galactosyltransferase gene as required by claim 67. Nevertheless, in order to expedite prosecution of the instant application, Applicants have limited claims 2 and 67 to cells *in vitro*. No new matter is added by these amendments.

In light of the above considerations, Applicants request that the rejections under 35 U.S.C. §112, first paragraph, be withdrawn.

Attached is a marked-up version of the changes being made by the current amendment.

CONCLUSIONS

Applicants submit that the pending claims patentably define the invention. Applicants request that the Examiner reconsider the rejections set forth in the Office Action, and permit the pending claims to pass to allowance.

If the Examiner would like to discuss any of the issues raised in the Office Action, Applicants' undersigned representative can be reached at the telephone number listed below.

Enclosed is a petition for an automatic extension of time with the required fee. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: 9/30/02

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Version with markings to show changes made

In the claims:

Please cancel claims 78 and 79.

Please amend claims 1-3 and 67 as follows:

1. (Five times amended) A purified and isolated nucleic acid molecule comprising a nucleic acid sequence selected from the group consisting of (1) nucleotides [90] 91 -1203 of the porcine nucleic acid sequence with SEQ ID NO: 7, (2) a sequence encoding a porcine polypeptide having α-1,3 galactosyltransferase activity and having the amino acid sequence of SEQ ID NO:10, and (3) a sequence complementary to the sequence of (1) or (2).

2. (Three times amended) A host cell [that is transformed with a] comprising a recombinant nucleic acid molecule comprising a nucleic acid sequence selected from the group consisting of (1) nucleotides [90] 91 -1203 of the porcine nucleic acid sequence with SEQ ID NO: 7, (2) a sequence [corresponding to the sequence of (1) within the scope of the degeneracy of the genetic code] encoding a porcine polypeptide having α-1,3 galactosyltransferase activity and having the amino acid sequence of SEQ ID NO:10, [(3) a sequence that encodes a porcine polypeptide having α-1,3 galactosyltransferase activity and that hybridizes with a sequence complementary to the sequence of (1) or (2) after a wash at 65°C in a buffer containing 0.1% SDS and SSC at a concentration between 0.05 x and 0.5 x ,] and [(4)] (3) a sequence complementary to the sequence of (1)[,] or (2) [or (3)], wherein the cell is *in vitro*.

3. (Thrice amended) A porcine α-1,3 galactosyltransferase encoded by a nucleic acid molecule comprising a nucleic acid sequence selected from the group consisting of (1) nucleotides [90] 91 -1203 of the porcine nucleic acid sequence with SEQ ID NO: 7, (2) a sequence [corresponding to the sequence of (1) within the scope of the degeneracy of the genetic code] a sequence encoding a porcine polypeptide having α-1,3 galactosyltransferase activity and having the amino acid sequence of SEQ ID NO:10, [(3) a sequence that encodes a porcine polypeptide having α-1,3 galactosyltransferase activity and that hybridizes with a sequence complementary to the sequence of (1) or (2) after a wash at 65°C in a buffer containing 0.1%

SDS and SSC at a concentration between 0.05 x and 0.5 x,] and [(4)] (3) a sequence complementary to the sequence of (1)[,] or (2) [or (3)], wherein the polypeptide is expressed from cell of claim 2 and is encoded by the recombinant nucleic acid molecule.

67. (Amended) A porcine cell comprising at least one disrupted α-1,3 galactosyltransferase gene, wherein the disruption is by insertion of an exogenous sequence into said gene such that the disruption prevents expression of functional α-1,3 galactosyltransferase and wherein the gene, prior to disruption, encodes the porcine α-1,3 galactosyltransferase with an amino acid sequence of SEQ ID NO:10, wherein the cell is *in vitro*.